

## LIST OF REFERENCES CITED BY APPLICANT

Atty Docket No.: 4910-2

Filing Date: March 07, 2000

Serial No.: 09/520,255

Group Art:

Applicant: Steve ROFFLER et al.

1c973 U.S. PTO  
09/810379  
03/16/01

## U.S. PATENT DOCUMENTS

*Ex. Intls.		Document No.	Date	Name	Class	Subclass	Filing Date
	AA						
	AB						

## FOREIGN PATENT DOCUMENTS

*Ex. Intls.		Document No.	Date	Country	Name	Class	Subclass	Translation Yes/No
	AC							
	AD							

## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AE	Klibanov et al., "Blood Clearance of Radiolabeled Antibody: Enhancement by Lactosamination and Treatment with Biotin-Avidin or Anti-Mouse IgG Antibodies", pp. 1951-1956, The Journal of Nuclear Medicine, Vol. 29, No. 12, Dec. 1988
AF	Yao et al., "Improved Targeting of Radiolabeled Streptavidin in Tumors Pretargeted with Biotinylated Monoclonal Antibodies through an Avidin Chase", pp. 837-841, The Journal of Nuclear Medicine, Vol. 36, No. 5, May. 1995
AG	Guermant et al., "Quantitative Determination of Polyethylene Glycol Based upon Its Salting Out and Partitioning of a Dye into the Resulting Aqueous Two-Phase System", pp. 254-258, Analytical Biochemistry 230, (1995)
AH	Kerr et al., "Application of Monoclonal Antibodies against Cytosine Deaminase for the in Vivo Clearance of a Cytosine Deaminase Immunoconjugate", pp. 353-357, Bioconjugate Chem., Vol. 4, No. 5, (1993)
AI	Pedley et al., "The effect of second antibody clearance on the distribution and dosimetry of radiolabelled anti- cea antibody in a human colonic tumor xenograft model", pp. 713-718, Int. J. Cancer 43, (1989)
AJ	Sharkey et al., "Enhanced Clearance of Radiolabeled Murine Monoclonal Antibody By a Syngeneic Anti-idiotypic Antibody in Tumor-Bearing Nude Mice", pp. 266-273, Int. J. Cancer, 51 (1992)
AK	Kinahan et al., "High-performance liquid chromatographic determination of PEG 600 in human urine", pp. 297-307, Journal of Chromatography, 565, (1991)
AL	Ruddy et al., "High-performance liquid chromatographic method for the simultaneous determination of low-molecular mass oligomers of polyethylene glycol in aqueous skin extracts", pp. 83-92, Journal of Chromatography B. 657 (1994)
AM	Kobayashi et al., "Comparison of the Chase Effects of Avidin, Streptavidin, Neutravidin, and Avidin-Ferritin on a Radiolabeled Biotinylated Anti-Tumor Monoclonal Antibody", pp. 310-314, Jpn. J. Cancer Res. 86, March 1995
AN	Zhang et al., "Intravenous Avidin Chase Improved Localization of Radiolabeled Streptavidin in Intraperitoneal Xenograft pretargeted with Biotinylated Antibody", pp. 61-64, Nuclear Medicine & Biology, Vol. 24, (1997)
AO	Sharkey et al., "Second antibody clearance of radiolabeled antibody in cancer radioimmunodetection", pp. 2843-2846, Proc. Natl. Acad. Sci. USA, Vol. 81, May 1985
AP	Nag et al., "A colorimetric Assay for Estimation of Polyethylene Glycol and Polyethylene Glycolated Protein Using Ammonium Ferrothiocyanate", pp. 224-231, Analytical Biochemistry 237, (1996)

Duplicate

09/03/2000  
Borden Feltz

1999

<del>mg</del>	<del>AQ</del>	<del>Cheng et al., "Accelerated Clearance of Polyethylene Glycol-Modified Proteins by Anti-polyethylene Glycol IgM", pp. 520-528, Bioconjugate Chemistry, Vol 10, No. 3, <u>date missing</u></del>
	AR	Cheng et al., "Efficient Clearance of Poly(ethylene glycol)-Modified Immunoenzyme with Anti PEG monoclonal Antibody for Prodrug Cancer Therapy", pp. 258-266, Bioconjugate Chemistry, Vol 11, No. 2, (2000)
	AS	Rogers et al., "Plasma clearance of an antibody - enzyme conjugate in ADEPT by monoclonal anti-enzyme: its effect on prodrug activation in vivo", pp. 1357-1363, British Journal of Cancer, 72, (1995)
	AT	Ryan et al., "Separation and Quantitation of Polyethylene Glycols 400 and 3350 from Human urin by High-Performance Liquid Chromatography", pp. 350-351, Journal of Pharmaceutical Sciences/351, Vol. 81, No. 4, April 1992
	AU	Marshall et al., "Galactosylated streptavidin for improved clearance of biotinylated intact and F(ab'), fragments of an anti-tumour antibody", pp. 18-24, British Journal of Cancer 71, (1995)
	AV	Sharma et al., "Inactivation and clearance of an anti-CEA carboxypeptidase G2 conjugate in blood after localisation in a xenograft model", pp. 659-662, Br. J. Cancer, 61, (1990)
	AW	Stocks et al., "A fluorometric Assay of the Degree of Modification of Protein Primary Amines with Polyethylene Glycol", pp. 232-234, Analytical Biochemistry 154, (1986)
	AX	
	AY	
✓	AZz	

Duplicate

EXAMINER:

DATE CONSIDERED:

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute for Form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		<b>Complete if Known</b>	
		Application Number	
		Filing Date	
		First Named Inventor	Steve ROFFLER
		Art Unit	1642
		Examiner Name	S. Ungar
Attorney Docket No.	4910-2DIV2		
Sheet	1	of	2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind-Code <sup>2</sup> (if known)			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind-Code <sup>5</sup> (if known)				

Substitute for Form 1449/PTO		<b>Complete if Known</b>	
		Application Number	
Examiner Signature	<i>Brendan F. [Signature]</i>	Date Considered	8/26/2003

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*Applicant's unique citation designation number (optional). \*See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \*Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \*For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \*Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \*Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form call 1-800-PTO-0100 (1-800-786-0100) and select option 2

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Filing Date	
		First Named Inventor	Steve ROFFLER
		Art Unit	1642
		Examiner Name	S. Ungar
Sheet 2 of 2		Attorney Docket Number	4910-2DIV2
<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SK		Klibanov et al., "Blood Clearance of Radiolabeled Antibody: Enhancement by Lactosamination and Treatment with Biotin-Avidin or Anti-Mouse IgG Antibodies", pp. 1951-1956, <u>The Journal of Nuclear Medicine</u> , Vol. 29, No. 12, Dec. 1988.	
SK		Yao et al., "Improved Targeting of Radiolabeled Streptavidin in Tumors Pretargeted with Biotinylated Monoclonal Antibodies through an Avidin Chase", pp. 837-841, <u>The Journal of Nuclear Medicine</u> , Vol. 36, No. 5, May, 1995.	
SK		Guermant et al., "Quantitative Determination of Polyethylene Glycol Based Upon Its Salting Out and Partitioning of a Dye into the Resulting Aqueous Two-Phase System", pp. 254-258, <u>Analytical Biochemistry</u> , 230, (1995).	
SK		Kerr et al., "Application of Monoclonal Antibodies Against Cytosine Deaminase for the In Vivo Clearance of a Cytosine Deaminase Immunoconjugate", pp. 353-357, <u>Bioconjugate Chem.</u> , Vol. 4, No. 5, (1999).	
SK		Pedley et al., "The Effect of Second Antibody Clearance on the Distribution and Dosimetry of Radiolabelled Anti-Cea Antibody in a Human Colonic Tumor Xenograft Model", pp. 713-718, <u>Int. J. Cancer</u> 43, (1989).	
SK		Sharkey et al., "Enhanced Clearance of Radiolabeled Murine Monoclonal Antibody by a Syngeneic Anti-idiotypic Antibody in Tumor-Bearing Nude Mice", pp. 266-273, <u>Int. J. Cancer</u> , 51 (1992).	
SK		Kinahan et al., "High-Performance Liquid Chromatographic Determination of PEG 600 in Human Urine", pp. 297-307, <u>Journal of Chromatography</u> , 565, (1991).	
SK		Ruddy et al., "High-Performance Liquid Chromatographic Method for the Simultaneous Determination of Low-Molecular-Mass Oligomers of Polyethylene Glycol in Aqueous Skin Extracts", pp. 83-92, <u>Journal of Chromatography B</u> , 657 (1994).	
SK		Kobabayashi et al., "Comparison of the Chase Effects of Avidin, Streptavidin, Neutravidin, and Avidin-Ferritin on a Radiolabeled Biotinylated Anti-Tumor Monoclonal Antibody", pp. 310-314, <u>Jpn. J. Cancer Res.</u> , 86, March 1995.	
SK		Zhang et al., "Intravenous Avidin Chase Improved Localization of Radiolabeled Streptavidin in Intraperitoneal Xenograft Pretargeted With Biotinylated Antibody", pp. 61-64, <u>Nuclear Medicine &amp; Biology</u> , Vol. 24 (1997).	
SK		Sharkey et al., "Second Antibody Clearance of Radiolabeled Antibody in Cancer Radioimmunodetection", pp. 2843-2846, <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 81, May 1985.	
SK		Nag et al., "A Colorimetric Assay for Estimation of Polyethylene Glycol and Polyethylene Glycolated Protein Using Ammonium Ferrothiocyanate", pp. 224-231, <u>Analytical Biochemistry</u> , 237, (1996).	
SK		Cheng et al., "Accelerated Clearance of Polyethylene Glycol-Modified Proteins by Anti-Polyethylene Glycol IgM", pp. 520-528, <u>Bioconjugate Chemistry</u> , Vol. 10, No. 3, 1999.	
SK		Cheng et al., "Efficient Clearance of Poly(ethylene glycol)-Modified Immunoenzyme with Anti PEG Monoclonal Antibody for Prodrug Cancer Therapy", pp. 258-266, <u>Bioconjugate Chemistry</u> , Vol. 11 No. 2 (2000)	
SK		Rogers et al., "Plasma Clearance of an Antibody-enzyme Conjugate in ADEPT by monoclonal Anti-Enzyme: Its Effect on Prodrug Activation in vivo", pp. 1357-1363, <u>British Journal of Cancer</u> , 72, (1995)	
SK		Ryan et al., "Separation and Quantitation of Polyethylene Glycols 400 and 3350 from Human Urine by High Performance Liquid Chromatography", pp. 350-351, <u>Journal of Pharmaceutical Sciences</u> , 351, Vol. 81, No. 4, April 1992)	

Examiner Signature	<i>Brendan K. [Signature]</i>	Date Considered	8/26/2005
--------------------	-------------------------------	-----------------	-----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* Applicant's unique citation designation number (optional). \* See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \* Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \* Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form call 1-800-PTO-0100 (1-800-786-9190) and select option 7

# BEST AVAILABLE COPY

PTO/SB/08A (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for Form 1449/PTO		<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> (Use as many sheets as necessary)		Application Number	
		Filing Date	
		First Named Inventor	Steve ROFFLER
		Art Unit	1642
		Examiner Name	S. Ungar
Sheet	1 of 1	Attorney Docket Number	4910-2DIV2
<b>NON PATENT LITERATURE DOCUMENTS</b>			
Examiner Initials*	Cite No. †	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ‡
JK		Marshall et al., "Galactosylated Streptavidin for Improved Clearance of Biotinylated Intact and F(ab)₂ Fragments of an Anti-Tumor Antibody", pp. 18-24, <i>British Journal of Cancer</i> , 71, (1995).	
AK		Sharma et al., "Inactivation and Clearance of an Anti-CEA Carboxypeptidase G2 Conjugate in Blood After Localization in a Xenograft Model", pp. 659-662, <i>British Journal of Cancer</i> , 61, (1990).	
JK		Stocks, et al., "A Fluorometric Assay of the Degree of Modification of Protein Primary Amines with Polyethylene Glycol", pp. 232-234, <i>Analytical Biochemistry</i> , 154, (1986).	

Examiner Signature	Brandon E. Hest	Date Considered	8/26/98
--------------------	-----------------	-----------------	---------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. † Applicant's unique citation designation number (optional). ‡ See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. † Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ‡ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. † Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ‡ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.